

Kamilche Sea Farms, Inc.

Premium Mussels - Fresh from Puget Sound

WA Cert. # 217SS

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April 17, 1999

William K. Hubbard
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Federal Register Request for Information: Performance Standard for *Vibrio vulnificus*, Docket Number 98P-0504- Volume 64, No.13. Page 3300-3301

Dear Mr. Hubbard,

I am a shellfish grower in Washington state, and would like to respond to the FDA's request for information on eight points regarding the Center for Science in the Public Interest's petition in the above referenced docket number. Specifically, I would like to contribute comments regarding Points 5 and 8.

Regarding Point Number 5, if there was indeed a public health threat from consumption of other species there might be some validity to the extension of performance standards to those species. So far as I am aware, though, there is no indication that species such as clams and mussels are implicated in vibrio-related illnesses. Our company is one of many along the West Coast that specializes in the culture and marketing of fresh, live mussels. The effect of applying a "zero tolerance" performance standard for *V. parahaemolyticus* on companies such as ours would be that we would be forced to use the Ameri-pure process. Since no one wants to purchase dead mussels which have been subjected to this procedure, we would have to shut our doors immediately. So the end result is that no discernible public health improvement is achieved, and hundreds of small family businesses such as ours are destroyed.

Regarding Point Number 8, performance standards need to be based on some body of empirical evidence that relates vibrio levels to risk of illness. Otherwise consumer and industry confidence is seriously eroded, for it becomes apparent that the performance standard established has no bearing on any degree of public health. (CSPI correctly points out that present performance standards are inadequate.) The best opportunity to gather such evidence to determine what constitutes an infectious dose for *V. parahaemolyticus* is to follow the ISSC's Interim Control Plan which was developed in 1998. If public health protection is the number one priority this is the most workable solution.

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I appreciate that the FDA is looking seriously at the problem of V. vulnificus. This is a killer that must be stopped. Many of us have grown resentful over the past few years that the Gulf Coast shellfish industry has been dodging this issue. But it is a bitter irony that, now when the FDA is squarely facing the issue, we on this coast risk being thrown overboard as well. This is despite the fact that the West Coast industry has made good faith and diligent efforts to tackle the less serious public health problem of V. parahaemolyticus.

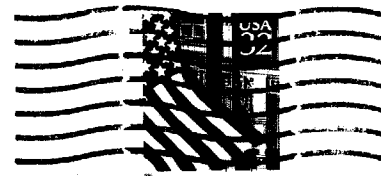
I urge the FDA to refer this matter to the ISSC as the proper vehicle for resolution of the problem. I also urge the agency to provide funding and research needed to develop appropriate, science-based criteria for establishing public health policy. Thank you for your consideration.

Sincerely,

A handwritten signature in cursive script that reads "Charlie Stephens".

Charlie Stephens, owner
Kamilche Sea Farms, Inc.

Kamilche Sea Farms
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